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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,404	05/21/2001	Douglas T. Dieterich	144002-2001	8918

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/862,404	DIETERICH, DOUGLAS T.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-12* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of Application, Amendments and/or Claims

The amendment filed 10 July 2003 (Paper No. 8) has been entered in full. Claims 13-16 are cancelled. Claims 1-12 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection of claims 1, 3-5 as set forth at page 3 of the previous Office Action (04 March 2003, Paper No. 7) is *withdrawn* in view of the amendment (10 July 2003, Paper No. 8).

The rejection of claim 5 under 35 USC 112, second paragraph as set forth at page 4 of the previous Office Action (04 March 2003, Paper No. 7) is *withdrawn* in view of the amendment (10 July 2003, Paper No. 8).

The rejection of claim 1 under 35 USC 102(b) as being anticipated by Weisz *et al.* (IDS#BW, Paper No. 4) as set forth at page 5 of the previous Office Action (04 March 2003, Paper No. 7) is *withdrawn* in view of the amendment (10 July 2003, Paper No. 8).

Claim Rejections - 35 USC § 102

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Bruchfeld *et al.* (Journal of the American Society of Nephrology, September 2000, Vol. 11, No. Program and Abstract Issue, pp. 57A). The basis for this rejection is set forth at pages 4-5 of the previous Office Action (04 March 2003, Paper No. 7).

Applicants state that Bruchfeld does not teach the combination therapy of using EPO (erythropoietin) and RBV (ribavirin) to control the anemic condition of patients since by so doing, Bruchfeld believes would result in side-effects for the dialysis and renal insufficient patients. Applicants maintain that Bruchfeld teaches away from the present invention in that it specifically discourages the use of ribavirin in any combination therapy.

Applicants' arguments have been fully considered but not deemed persuasive. Bruchfeld *et al.* clearly state in the conclusion that ribavirin can be used in renal insufficiency and dialysis but requires reduced ribavirin doses as well as close monitoring of ribavirin concentrations. Bruchfeld *et al.* teach that ribavirin induced anemia can be managed with erythropoietin. The evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 103

Claims 2-5, 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchfeld *et al.* (Journal of the American Society of Nephrology, September 2000, Vol. 11, No. Program and Abstract Issue, pp. 57A) in view of Niitsu *et al.* (US Patent No. 6,268,336 B1). The basis for this rejection is set forth at pages 5-7 of the previous Office Action (04 March 2003, Paper No. 7).

Applicants state that Niitsu relates to a pharmaceutical composition for treatment of hepatic diseases. Applicants cite In re Fritch and Ex parte Obukowicz. Applicants contend that the picking and choosing from both of the cited references to allege that

the instant invention is obvious simply fails in light of the case law under Section 103. Applicants state that none of the cited references, alone, or in any combination, render the invention prima facie obvious.

Applicants' arguments have been fully considered but not deemed persuasive. As was stated above in the 102 rejection, Bruchfeld *et al.* state that RBV can be used in renal insufficiency and dialysis. Bruchfeld *et al.* teach the use of EPO. Niitsu *et al.* teach that venesection anemia in hepatitis C patients can be treated with EPO. Both references teach the use of EPO for treating anemia in hepatitis C patients. Therefore, it would have obvious to one of ordinary skill in the art to modify the method of Bruchfeld *et al.* by using the routes of administration of EPO taught by Niitsu *et al.* The motivation to do so and reasonable expectation of success is provided by Bruchfeld *et al.* who state that RBV induced anemia can be managed with EPO. The evidence as a whole indicates that the rejection should be maintained.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weisz *et al.* (IDS#BW, Paper No. 4) in view of Niitsu *et al.* (US Patent No. 6,268,336 B1) and Perez-Olmeda *et al.* (Abstract, Journal of Acquired Immune Deficiency Syndromes, 1999 22 (3) pg 308-309).

Weisz *et al.* teach the administration of RBV, IFN and EPO in patients co-infected with HIV and hepatitis C virus (HCV). Weisz *et al.* teach that RBV induced anemia can be treated with EPO. Weisz *et al.* do not teach liquid preparations or routes

of administration of EPO. Weisz *et al.* do not disclose the HCV genotype of the patients.

Niitsu *et al.* teach the administration of EPO to treat venesection induced anemia in hepatitis C patients (column 1, lines 52-60; column 2, lines 17-21 and column 3, lines 44-55). Niitsu *et al.* teach that EPO is dissolved in a saline for administration (liquid preparation of EPO) (column 3, lines 21-30). Niitsu *et al.* teach administration of EPO units that overlap with the instant claims (column 3, lines 34-43). Niitsu teaches that hepatitis C patients were subjected to weekly venesection and after every venesection, EPO was subcutaneously administered.

Perez-Olmeda *et al.* teach the administration of RBV and IFN-alpha in patients co-infected with HIV and HCV genotype 3.

Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Weisz *et al.* using the routes of administration of EPO as taught by Niitsu *et al.* in patients co-infected with HIV and HCV genotype 3 taught by Perez-Olmeda. The motivation to do so and reasonable expectation of success is provided by Weisz *et al.*, who teach that RBV induced anemia can be treated with EPO in patients co-infected with HIV and HCV and Perez-Olmeda *et al.* who teach the administration of RBV and IFN-alpha in patients co-infected with HIV and HCV genotype 3.

Claim Objections

Claim 6 is objected to for depending from a rejected claim.

Conclusion

Claims 1-5, 7-12 are rejected.

Claim 6 is objected to.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
October 2, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600